

1449s and return them to applicant with the next Office Action. Additional IDSs were also filed on July 24, 2002, September 27, 2002 and November 15, 2002, i.e. after the mailing of the outstanding Office Action.

Applicant notes that there are a number of inconsistencies in the statements of rejection. More specifically:

1. Page 1 of the Office Action indicates that claims 14, 15 and 25 have been objected to, while page 2 indicates that claims 14, 15 and 25 have been rejected.
2. Further to the rejection of claims 14 and 15, page 2 of the Office Action indicates that these claims have been rejected as being purportedly anticipated by the Avitall patent. However, although claims 14 and 15 depend from claim 13, the Office Action does not indicate that claim 13 has also been rejected based on the Avitall patent.
3. Page 2 of the Office Action indicates that claim 13 has been rejected as being purportedly anticipated by the Imran patent. Although claim 13 depends from claim 11, there is no indication that claim 13 has also been rejected based on the Imran patent.

Accordingly, for the purposes of this response, applicant has assumed that claims 13-15 and 25 have been rejected based on the Avitall patent and that claim 11 has been rejected based on the Imran patent. Nevertheless, applicant respectfully requests that the rejections be clarified in the next Office Action.

## II. BRIEF DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present inventions, as defined by the claims, are directed generally to structures that support tissue coagulation devices. Certain aspects of the inventions are illustrated, for example, in Figures 14, 16A and 16B. Referring first to Figure 14, an exemplary catheter 90 is used in combination with a sheath 92. The sheath 92 has a distal member 94 that is connected to the distal end of the catheter 90. This allows the catheter 90 to bulge outwardly from the sheath 92 in the manner illustrated in Figure 14 when the catheter is urged distally relative to the sheath. The catheter 90 also supports an **inflatable** tissue coagulation body 20. The exemplary inflatable tissue coagulation

body 20, which is shown in its uninflated and inflated states in Figures 16A and 16B, may be inflated by supplying liquid under pressure to the tissue coagulation body.

Catheters in accordance with some of the present inventions may include a tissue coagulation body and a hinge which defines the apex of a loop that may be formed with the catheter. Referring to the exemplary implementation illustrated in Figures 16A and 16B, the hinge 76 has a flexibility which allows the apex of the loop to be inserted into the pulmonary vein to such an extent that the tissue coagulation body 20 will be substantially aligned with the pulmonary vein ostium.

### **III. REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH**

Claim 20 has been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. More specifically, the Examiner indicated that there was some question concerning the function of the "slot." Applicant respectfully submits that one example of a device in accordance with claim 20 is illustrated in Figure 14 and described at, for example, page 18, lines 6-20 of the specification. The specification states that the slot is the region where the sheath material has been removed, and that the catheter 90 bulges out of the sheath 92 through the slot to form the loop 98. In view of the foregoing, applicant respectfully submits that one of skill in the art would understand the invention defined by claim 20 and that the rejection of claim 20 under 35 U.S.C. § 112, second paragraph, should be withdrawn.

### **IV. PRIOR ART REJECTIONS**

#### **A. The Rejections**

Claims 11-15, 21-25 and 27 have been rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 5,263,493 to Avitall (the Avitall '493 patent). Claims 11 and 13 have been rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No.

5,782,899 to Imran (the Imran '899 patent). Claims 16 and 26 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the Avitall '493 patent and U.S. Patent No. 5,738,683 to Osypka (the Osypka '683 patent). Claims 17 and 28 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the Avitall '493 patent and U.S. Patent No. 5,967,984 to Chu (the Chu '984 patent). Claims 18 and 29 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the Avitall '493 patent and U.S. Patent No. 5,213,576 to Abiuso (the Abiuso '576 patent). Claims 19 and 30 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the Avitall '493 patent and U.S. Patent No. 5,380,319 to Saito (the Saito '319 patent).

The rejections under 35 U.S.C. §§ 102 and 103 are respectfully traversed. Reconsideration thereof is respectfully requested.

#### **B. Discussion Concerning Claims 11-20**

Independent claim 11 calls for a combination of elements comprising “an outer member defining a distal end and including a wall defining an interior bore,” “an elongate body carried within the outer member interior bore and defining a distal region and a distal end operably connected to the distal end of the outer member” and “***an inflatable tissue coagulation body supported on the elongate body distal region.***”

The Avitall '493 patent fails to teach or suggest such a combination. For example, the Avitall '493 patent is directed to catheters with loop structure 20 and 120. In clear contrast to the claimed combination of elements, the loop structures 20 and 120 do not support an ***inflatable*** tissue coagulation body. To the contrary, the loop structures 20 and 120 respectively support electrodes 36 and 136. As the Avitall '493 patent fails to teach or suggest each and every element of the combination recited in independent claim 11, applicant respectfully submits that claims 11-15 are patentable thereover and that the rejection under 35 U.S.C. § 102 is improper and must be withdrawn.

Turning to dependent claims 16-20, applicant respectfully submits that the Osypka '683, Chu '984, Abiuso '576 and Saito '319 patents fail to remedy the above-identified deficiencies in the Avitall '493 patent. Accordingly, claims 16-20 are, at a minimum, patentable for at least the same reasons as independent claim 11 and the rejections thereof under 35 U.S.C. § 103 should also be withdrawn.

The Imran '899 patent discloses a mapping and ablation system that includes a probe 12, with an expandable basket 27, and a catheter 13. In clear contrast to the claimed combination of elements, the catheter 13 and basket 27 do not support an **inflatable** tissue coagulation body. To the contrary, the catheter 13 supports an electrode 54 and the basket 27 supports a plurality of mapping electrodes 26. As the Imran '899 patent fails to teach or suggest each and every element of the combination recited in independent claim 11, applicant respectfully submits that claims 11-13 are patentable thereover and that the rejection under 35 U.S.C. § 102 is improper and must be withdrawn.

### C. Discussion Concerning Claims 21-30

Independent claim 21 calls for a combination of elements comprising "a tissue coagulation body" and "an elongate body ... including a hinge portion defining the apex of the loop formed by distal region, the ***hinge portion having a flexibility that allows the apex of the loop to be inserted into a pulmonary vein to such an extent that the tissue coagulation body will be substantially aligned with the pulmonary vein ostium.***"

The Avitall '493 patent fails to teach or suggest such a combination. For example, nothing in the Avitall '493 patent remotely suggests that the loop structures 20 and 120 disclosed therein have the flexibility features set forth in independent claim 21. The Avitall '493 patent does not even include the phrase "pulmonary vein." As the Avitall '493 patent fails to teach or suggest each and every element of the combination recited in independent claim 21, applicant respectfully submits that claims 21-25 and 27

are patentable thereover and that the rejection under 35 U.S.C. § 102 is improper and must be withdrawn.

Turning to dependent claims 26 and 28-30, applicant respectfully submits that the Osypka '683, Chu '984, Abiuso '576 and Saito '319 patents fail to remedy the above-identified deficiencies in the Avitall '493 patent. Accordingly, claims 26 and 28-30 are, at a minimum, patentable for at least the same reasons as independent claim 21 and the rejections thereof under 35 U.S.C. § 103 should also be withdrawn.

#### IV. CLOSING REMARKS

In view of the foregoing, it is respectfully submitted that the claims in the application are in condition for allowance. Reexamination and reconsideration of the application, as amended, are respectfully requested. Allowance of the claims at an early date is courteously solicited.

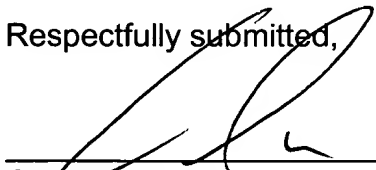
If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is respectfully requested to call applicant's undersigned representative at (310) 563-1458 to discuss the steps necessary for placing the application in condition for allowance.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0638. Should such fees be associated with an extension of time, applicant respectfully requests that this paper be considered a petition therefor.

11/13/02  
Date

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Respectfully submitted,

  
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